510(K) SUMMARY

DEC 2 7 2005

K052678

This summary of 510(k) safety and effectiveness information is being submitted in accordance the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Name: **Limax ELECTRONICS CO., LTD.**

Address: 5 F-1, No. 176, Keelung Road, Sec. 1 , 11069, Taipei , Taiwan
Phone: 886-2-2769 9969
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Contact: Mr. William Chiu / President

2.0 Device Name: **AQ-830 Slim Body, Body Fat Monitor**

3.0 Predicate Device:

- LONG WELL LW-6Dxx Body Fat Analyzer (K030203) marketed by LONG WELL ELECTRONICS CORP. &
- Omron HBF-306 Body Fat Analyzer (K011652)marketed by Omron Healthcare INC.

4.0 Device Description: **AQ-830 Slim Body, Body Fat Monitor** is a hand-held, non-sterile, reusable Body Fat Analyzer intended for estimation of the body fat of percentage in the home.

5.0 Intended Use: The **AQ-8303 Slim Body, Body Fat Monitor** is intended for estimation of the body fat of percentage in the home..

6.0 Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included IEC 60601-1 and IEC 60601-1-2 requirements. Moreover, A comparison study with device that use DEXA(Dual energy X-ray absorptiometry) technology was performed to validate the performance of the **AQ-830 Slim Body, Body Fat Monitor.**

Subjects were grouped as male/ female, ages. The comparison study demonstrated that the clinical repeatability of **AQ-830 Slim Body, Body Fat Monitor** is statistically and clinically acceptable in all age/weight/height groups.

7. Conclusions:

The **AQ-830 Slim Body, Body Fat Monitor** have the same intended use and similar technological characteristics as **LONG WELL LW-6Dxx Body Fat Analyzer (K030203) marketed by LONG WELL ELECTRONICS CORP.** and **Omron HBF-306 Body Fat Analyzer(K011652)marketed by Omron Healthcare INC.**. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise and new questions of safety or effectiveness. Thus, the **AQ-830 Slim Body, Body Fat Monitor** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2005

LIMAX ELECTRONICS CO., LTD.
c/o Ms. Jennifer Reich
Harvest Consulting Corp.
2904 N. Boldt Drive
FLAGSTAFF AZ 86001

Re: K052678
Trade/Device Name: AQ-830 Slim Body, Body Fat Monitor
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: September 27, 2005
Received: September 28, 2005

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: **AQ-830 Slim Body, Body Fat Monitor**
Limax ELECTRONICS CO., LTD.

Indications For Use:

The device is a noninvasive bioimpedance meter used to estimate body fat percentage in the home setting. The device is for normal, healthy people only, and the applicable age range is 10 to 80 years old.

The device is to be used in a home environment having normal temperature and humidity conditions.

Prescription Use _____ AND/OR Over-The-Counter Use V
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Lepson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052678